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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SETA SAAD and CHRISTIAN E. SAAD, individually and as representatives of the Estate of Raymond Saad,

Plaintiffs,

v.

GUIDANT CORPORATION; GUIDANT SALES CORPORATION; CARDIAC PACEMAKERS, INC.; BOSTON SCIENTIFIC CORPORATION; ASHLEY & MCMULLEN-WING SUN MORTUARY, a business entity form unknown, ASHLEY & MCMULLEN, a business entity form unknown; and DOES 1 through 20, inclusive,

Defendants.

Case No: C 08-00053-PJH

DECLARATION OF JEREMY R. FIETZ IN SUPPORT OF MOTION FOR REMAND

Hearing Date: February 20, 2007

Time: 9:00 a.m.

Location: Courtroom 3, 17th Floor

Honorable Phyllis J. Hamilton

Removal Filed: January 4, 2008

I, JEREMY R. FIETZ, declare as follows:

1. I am an attorney licensed to practice in all of the courts of the state of California as well as the Northern District Court. I am a partner with the Edgar Law Firm, counsel for plaintiffs. As such I have personal knowledge of the following:

2. I have personal knowledge of the following facts and, if called as a witness could and would competently testify thereto.

3. A true and correct copy of the Complaint in this matter is attached hereto as Exhibit A.

4. In an effort to meet and confer on the issues presented by the within motion, my firm contacted counsel for Guidant to request that they stipulate to remand this matter to State court. Counsel for Guidant, Mia Solvesson, confirmed that Guidant defendants would not stipulate to remand.

5. I have expended at least 10 hours in the preparation of this motion.

6. My reasonable and customary hourly fee is $250.00.

7. Pursuant to 28 U.S.C. 1447(c), I hereby request fees in the amount of ($250.00 x 15) $2500.00.

I declare under penalty of perjury under the laws of the State of California that the forgoing is true and correct and that this declaration was executed in Santa Rosa, California, on January 16, 2008.

JEREMY R. FIETZ, ESQ.
Declarant

PROOF OF SERVICE

I am employed in the City and County of Santa Rosa, State of California. I am over the age of 18 and not a party to the within action. My business address is 408 College Avenue, Santa Rosa, California 95401. On January 16, 2008, I served the foregoing document(s) described as:

DECLARATION OF JEREMY R. FIETZ IN SUPPORT OF MOTION FOR REMAND

on the interested parties by placing ( ) the original (X) a true and correct copy thereof in a sealed envelope addressed as follows:

Dana N. Gwaltney, Esq.
SHOOK HARDY & BACON LLP
333 Bush Street, Suit 600
San Francisco, CA 94104-2828
Telephone: 415/544-1900
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Attorneys for Guidant Corporation, Guidant Sales Corporation; Cardiac Pacemakers, Inc., and Boston Scientific Corproation

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Attorneys for Cathay Mortuary Wah Sang Inc. dba Ashley & McMullen Mortuary

[X] VIA OVERNIGHT MAIL:

VIA : By delivering such documents to an overnight mail service or an authorized courier in an envelope or package designated by the express service courier addressed to the person(s) on whom it is to be served.

[ ] VIA U.S. MAIL:

I am readily familiar with the firm's practice for collection and processing of correspondence for mailing. Under that practice such envelope(s) would be deposited with the U.S. postal service with postage thereon fully prepaid, at Santa Rosa, California.

[X] FEDERAL:

I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

I declare under penalty of perjury under the laws of the state of California that the above is true and correct and was executed on January 16, 2008

JEREMY R. FIETZ

EXHIBIT A

ENDORSED
FILED
San Francisco County Superior Court
OCT 29 2007
GORDON PARK-LI, Clerk
BY: JUN P. PANELO
Deputy Clerk

Donald S. Edgar, Esq. (State Bar No. 139324)
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Attorneys for all Plaintiffs

CASE MANAGEMENT CONFERENCE SET

MAR 28 2008 -9:00 AM

DEPARTMENT 212

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF SAN FRANCISCO

SETA SAAD and CHRISTIAN E. SAAD, individually and as representatives of the Estate of RAYMOND SAAD,

Plaintiffs,

v.

GUIDANT CORPORATION; GUIDANT SALES CORPORATION; CARDIAC PACEMAKERS, INC.; BOSTON SCIENTIFIC CORPORATION, ASHLEY & MCMULLEN-WING SUN MORTUARY, a business entity form unknown; ASHLEY & MCMULLEN, a business entity form unknown; and DOES 1 through 20, inclusive,

Defendants.

CASE NO.: CGC-07-468614

UNLIMITED CIVIL

COMPLAINT FOR DAMAGES, RESTITUTION, and INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs, by their undersigned counsel, individually and in their representative capacities, hereby bring this Complaint against Defendants GUIDANT CORPORATION ("Guidant Corp."), GUIDANT SALES CORPORATION ("Guidant Sales"), CARDIAC PACEMAKERS, INC. ("CPI") and BOSTON SCIENTIFIC CORPORATION ("Boston Scientific") (all hereinafter collectively referred to as "Defendants" or "Guidant" or "Guidant Defendants"), ASHLEY &

MCMULLEN-WING SUN MORTUARY, ASHY & MCMULLEN, and DOES 1 through 20, for compensatory, equitable, and injunctive relief. Plaintiffs make the following allegations based upon their personal knowledge with respect to their own acts, and, upon information and belief, as well as upon their respective attorneys' investigative efforts, as to the actions and misconduct of GUIDANT, ASHLEY & MCMULLEN-WING SUN MORTUARY and ASHLEY & MCMULLEN.

PARTIES

2. Plaintiff RAYMOND SAAD was a citizen and resident of the State of California. Mr. Saad had a severe cardiovascular condition that necessitated the use of an implantable cardiac pacemaker/defibrillator. On or about October 7, 2004, Mr. Saad was implanted with a Guidant Contak Renewal cardiac resynchronization therapy defibrillator, also known as the "CRT-D," or the "Model H135." On or about October 30, 2005, Mr. Saad died of heart failure.

3. Plaintiff SETA SAAD is a citizen and resident of the State of California. She is the widow and successor-in-interest of RAYMOND SAAD.

4. Plaintiff CHRISTIAN E. SAAD is a citizen and resident of the State of California. He is the son and successor-in-interest of RAYMOND SAAD.

5. Defendant GUIDANT CORP. is an Indiana corporation, with its principal place of business at 111 Monument Circle, 29th Floor, Indianapolis, Indiana. Guidant Corp. develops technology to treat conditions such as heart disease, neurological disorders, and vascular illness. Guidant's CRM Division is the division that develops, researches, advertises, promotes, markets, and sells all of Guidant's ICDs, some of which are marketed under the trade names Ventak Prizm, Contak Renewal, and Vitality. CRM Division's operations are principally conducted out of its facilities at 4100 Hamline Avenue North, St. Paul, Minnesota.

6. Defendant GUIDANT CORP. sells its ICDs and pacemakers through its wholly-owned subsidiary, Defendant GUIDANT SALES CORPORATION. Guidant Sales is an Indiana corporation, with its principal place of business at 111 Monument Circle in Indianapolis, Indiana.

7. Defendant CARDIAC PACEMAKERS, INC., a Minnesota corporation, developed Guidant's ICDs and pacemakers. CPI was merged into Guidant in or about September 1994, and is now a wholly-owned subsidiary of Guidant Corp., with headquarters at 4100 Hamline Ave. North,

St. Paul, Minnesota.

8. Defendant BOSTON SCIENTIFIC describes itself as a worldwide developer, manufacturer, and marketer of medical devices, whose products are used in a broad range of interventional medical specialties with reported revenue of $6.3 billion in 2005. Boston Scientific is incorporated in the State of Delaware with its principal executive office located in Natick, Massachusetts. In January 2006, Boston Scientific entered into an agreement to acquire Guidant Corp. and its subsidiaries for approximately $27 billion. Pending final approval of that merger, which has been approved by Guidant 's stockholders, Boston Scientific is the successor in interest to Guidant and, directly or indirectly, has assumed Guidant's liabilities in this litigation.

9. Defendant ASHLEY & MCMULLEN-WING SUN MORTUARY is a business entity, form unknown, that operates a mortuary located at 4200 Geary Boulevard, San Francisco, CA 94118.

10. Defendant ASHLEY & MCMULLEN is a business entity, form unknown, that operates the aforementioned mortuary, located at 4200 Geary Boulevard, San Francisco, CA 94118.

11. Plaintiffs are ignorant of the true names and capacities of those Defendants named as DOES 1 through 20 (hereinafter "Doe Defendants"), and for that reason have sued these Defendants by fictitious names. Plaintiffs are informed and believe, and on that basis allege, that each of the fictitiously named Defendants are in some way liable and legally responsible for the damages and injuries set forth in this Complaint. Plaintiffs will seek leave of the Court to amend this Complaint to identify these Defendants when their identities are determined.

12. In doing the things alleged in this Complaint, Defendants acted as the agents, servants, employees and alter-egos of their Co-Defendants. Defendants acted within the course and scope of their agency and employment, and acted with knowledge, consent and approval of their Co-Defendants. Their conduct was approved and ratified by their Co-Defendants.

JURISDICTION AND VENUE

13. This Court has jurisdiction over all causes of action asserted in this Complaint pursuant to the *California Constitution*, Article VI, § 10, because this case is a cause of action not assigned by statute to other trial courts.

14. This Court has jurisdiction over each Defendant named in this Complaint because

each Defendant is an individual who is either domiciled in California or has sufficient minimum contacts with California so as to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

15. Venue is proper in this Court in accordance with *California Code of Civil Procedure* § 395 (a), because the injuries complained of in this Complaint were injuries to a person or persons, and were also injuries leading to death from a wrongful act or negligence, and said injuries occurred either entirely or substantially in the County where this Court sits.

16. The relief sought by each individual Plaintiff is within the jurisdictional limits of this Court.

FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS

I. GUIDANT CORPORATE STRUCTURE

17. Guidant Corp. and its wholly-owned subsidiaries, Guidant Sales and CPI, design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell products that treat cardiac arrhythmias, heart failure, and coronary and peripheral vascular disease. Guidant Corp.'s core biomedical businesses are divided into four divisions: Cardiac Rhythm Management, Cardiac Surgery, Endovascular Solutions, and Vascular Intervention.

18. Guidant Corp.'s products are sold through a combined sales organization, Guidant Sales.

19. Guidant Corp.'s business units present themselves under the "Guidant" corporate banner to the general public, including to the Food and Drug Administration ("FDA"), physicians, and individuals. As the Independent Panel that reviewed Guidant Corp.'s device surveillance and disclosure policies concluded, "the public views Guidant Corporation as a single entity, rather than a group of individual businesses." (See *Independent Panel Report*, at p. 16). Guidant Corp. promotes such a view by, among other things, including the Guidant logo on all device marketing materials.

20. Guidant Corp.'s business units have their own officers but are also tied together at the corporate level by a structure by which Guidant Corp. oversees the business units, including through the Guidant Management Committee.

21. The products of Guidant Corp.'s CRM Division include ICDs, pacemakers, and lead systems. ICDs are implanted medical devices used to detect and treat abnormally fast and irregular heart rhythms, each of which can stop or hinder the heart from pumping blood effectively throughout the body and can result in sudden cardiac death. Pacemakers are medical devices used to detect and treat abnormally slow heart rhythms.

22. Guidant holds itself out as "the world leader in the design and development of cardiovascular medical products." (See Guidant Corp., Corporate Overview, http://www.Guidant.com/about_us.shtml). ICDs have been Guidant Corp.'s fastest growing product for at least the last three years. The first ICD was placed on the market in 1985 by CPI, now wholly-owned by Guidant Corp. Between 2002 and 2004, Guidant Corp.'s revenues for sales of ICDs jumped 80% to $1.786 billion.

II. OVERVIEW OF IMPLANTABLE DEVICES FOR CARDIAC RHYTHM MANAGEMENT

23. Cardiovascular disease is the leading cause of death for both men and women in the United States. Implantable devices for cardiac rhythm management have become an integral part of cardiovascular therapy. Implantable pacemakers for individuals with bradycardia (a slow heartbeat) were introduced more than 40 years ago, and the first ICD was implanted in 1980. (As used hereinafter, the term "Implantable Device" will refer to pacemakers and/or ICDs manufactured and sold by Defendants.). Thereafter, specialized pacemakers called cardiac resynchronization devices that improve the mechanical function of the heart were introduced and combined with existing ICD technology. Today, Implantable Devices are also commonly used for treatment of arrhythmia (an irregular heartbeat).

24. There has been explosive growth in ICD use. There are now, in just the United States, well over one million individuals living with an implanted cardiac rhythm device and this number is increasing rapidly. In 2005, approximately 200,000 people in the United States were implanted with ICDs.

25. The ICDs designed, manufactured and distributed into the stream of commerce by Guidant consist of three components: (1) a small rectangular generator, approximately two inches

wide, which is implanted under the skin just below the collarbone; (2) insulated wires– or leads– which are attached to the generator and threaded through a vein to the heart, to carry the electric current from the generator; and (3) two electrodes, located at the tip of each lead, which deliver an electric shock to the heart.

26. The purpose of the ICD is to correct abnormal heart rhythm. The ICD can generate a series of precisely timed, low-intensity, electrical pulses to reset the heart to normal rhythm when the heart beats faster than normal (tachycardia); or the ICD can deliver sudden shocks to the heart to stop potentially fatal heart quivering (ventricular fibrillation). In addition, the ICD may be programmed as a pacemaker to send small electric signals if the heart beats too slowly (bradycardia).

27. Implantable CRT-D devices are medical devices that treat heart failure by helping the lower chamber (ventricles) pump synchronously with the upper chambers (atria), while preventing the heart from beating too slowly (bradycardia) and shocking or "over-drive pacing" of heartbeat rhythms that are too fast (a process by which the CRT-D is paced briefly at a rhythm faster than the desired rhythm in order to recapture control of the heartbeat).

28. All ICDs function as both pacemakers and defibrillators. The ICD can detect and correct both fast and slow heart rates. The ICD corrects the slow rates and can "over-drive pace" rapid rates and it also can administer shocks to treat ventricular tachycardia and ventricular fibrillation.

29. ICDs are used in individuals, like Plaintiffs, who have arrhythmias or irregular heartbeats that are considered life-threatening. These can include individuals with ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), ventricular tachycardia (excessively rapid heartbeat) that is poorly controlled by medication, or significant thickening of the heart muscle resulting in arrhythmia. Such conditions can result in the loss of consciousness or death, unless the affected individual receives therapy from an appropriate device to put the heart back into a normal cardiac rhythm. Pacemakers are used in individuals, like Plaintiffs, who have bradycardia that is uncontrolled by medicine alone.

30. If an implanted ICD operates properly, it can save an individual's life. If it fails to operate properly, the individual could die within minutes.

31. Since 1958, pacemakers have been sold for implantation in individuals who have had certain spontaneous and/or inducible life-threatening arrhythmias, bradycardia, heart block, and congestive heart failure and those who are at high risk of developing bradycardia, heart block, or arrhythmias. Pacemakers are used to manage disorders that disrupt the heart's normal electrical conduction system.

32. Pacemakers are designed to be implanted under the skin of the chest wall. The device's power source (pulse generator) is implanted in a pouch formed under the collarbone, just under the skin, usually on the upper left chest. Wires, called leads, are inserted through a blood vessel and attached directly into the heart. These wires, which are connected to the pacemaker or pulse generator, are capable of both sensing a problematic heart rate and stimulating a more appropriate heart rate.

33. Some individuals are very dependent on pacemakers to maintain an adequate heart rate, and therefore, cardiac output. For these individuals, failure of the cardiac pacemaker to provide pacing can cause sudden faintness, or loss of consciousness, and can result in death.

34. At all times relevant, Guidant misrepresented the safety of its ICDs and pacemakers and negligently manufactured, marketed, advertised, promoted, sold, and distributed those ICDs and pacemakers as safe devices to be used for treatment of individuals with prior myocardial infarction, arrhythmias, and individuals who are at high risk for developing such arrhythmias.

III. THE DEVICE AT ISSUE

35. As detailed below, this Complaint seeks recovery for injuries arising from the implantation of Guidant's Contak Renewal 1 Model H135, hereinafter referred to as the "H135 Device" or the "Device." The H135 Device is a heart regulating device, or defibrillator.

IV. THE FEDERAL REGULATORY SCHEME GOVERNING DESIGN, TESTING DISTRIBUTION AND RECALL OF THE DEVICE

36. As part of the conditions of approval for the Device, Defendants must ensure that no changes be made to the Device that would affect its safety or effectiveness without submission of a Pre-Market Approval ("PMA") supplement for review and approval, and that a PMA supplement

must be submitted when a device failure necessitates a labeling, manufacturing, or device modification. Violation of such conditions voids their approval.

37. The removal of Device from the market and other corrective actions taken by Guidant have been classified as Class I or Class II recalls under federal regulations–the highest levels of such recalls.

38. Under federal regulation "[r]ecall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." (21 C.F.R. § 7.3(g) (2006)).

39. The classification of a recall as Class I, II, or III "indicate[s] the relative degree of health hazard presented by the product being recalled."(*Id.* § 7.3(m)). "Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." (*Id.* § 7.3 (m)(1)). "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." (*Id.* § 7.3 (m)(2)).

40. A device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with federal regulations. (*See* 21 U.S.C. § 351 (2006)).

41. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. (*See* 21 U.S.C. § 352).

42. Manufacturers are required to comply with FDA regulation of medical devices, including FDA regulations relating to records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that

the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *(See* 21 U.S.C. § 360i).

43. Adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. (*See* 21 C.F.R. § 803.50).

44. Manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. (*See* 21 C.F.R. § 803.52).

45. Manufacturers must report to the FDA in five business days after becoming aware of any reportable medical device reporting ("MDR"). MDR events require the manufacturer to conduct a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. (*See* 21 C.F.R. § 803.53).

46. Device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total

number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. (*See* 21 C.F.R. § 806.10).

47. Manufacturers must comply with quality system regulations that require manufacturers to meet design-control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming product and take corrective action to prevent recurrence. Manufacturers are required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. (*See generally* 21 C.F.R. § 820).

48. A manufacturer must report to the FDA through a PMA supplement any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device. A manufacturer may implement changes to a device that enhance the safety of the device prior to obtaining FDA approval, if the manufacturer submits a special report entitled: "Special PMA Supplement -Changes Being Effected" and provides a full explanation of any labeling changes or changes in quality control or manufacturing process that add a new specification of test method, or otherwise provide additional assurance of purity, strength, or reliability of the device.

49. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." (Conditions of Approval at 1, attached to FDA Approval Letter from Daniel G. Schultz, Deputy Director for Clinical Policy, FDA, to Kaye Anderson, Senior U.S. Regulatory Affairs Associate, Guidant Corporation (July 18, 2002); *see* 21 C.F.R. § 814.39).

50. Guidant's failure to meet federal regulations applicable to medical devices and Guidant's other acts and omissions as described herein directly and proximately caused the H135

Device to be in violation of federal law and unfit for sale, and proximately caused harm, injury, and, in the case of Raymond Saad, death

51. Plaintiffs' state law claims are based on parallel state law provisions that do not conflict with federal law.

V. HISTORY OF THE DEVICE

52. As previously noted, Guidant manufactured CRT-D, also known as Contak Renewal Model H135.

53. In or before November 2003, Guidant became aware that the H135 Device was prone to short-circuiting.

54. From November 2003 to May 2005, Guidant knew of multiple instances in which the H135 Device had short circuited, including that the short circuiting had resulted in at least one death.

55. While Guidant knew that the H135 Device was defective, it failed to disclose the defect to the FDA, the medical community, and the public, and continued to sell the H135 Device with the defect. Not until September 2004 did Guidant consider stopping the sale of the defective device, and even then, determined that the Guidant sales staff should misrepresent to the medical community the reason for any resulting inventory back-orders in order to avoid questions that could lead to explanation of existing defective device.

56. In January 2005, Guidant considered withdrawing the H135 Device from the market because of the defect, but concluded that Guidant would not disclose the defect or withdraw the device from the market.

57. On June 17, 2005, only after Guidant had been forced to disclose the defects in other Guidant devices (for instance, the Ventak Prizm 2 DR 1861) and the FDA had initiated a review of these other devices, did Guidant issue a letter to doctors disclosing the defective nature of the H135. Specifically, as to the H135, Guidant stated that its laboratory analysis had proven that the Contak Renewal 1 & 2 had failed due to "deterioration in a wire insulator within the lead connector block [which,] in conjunction with other factors, could cause a short circuit and loss of device function due to diversion of therapy energy away from the heart and into device circuitry." (Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Contak Renewal Model H135 and

Contak Renewal 2 Model H155 Devices Manufactured on or Before August 26, 2004 at 1 (June 17, 2005) ("June 17 Contak Renewal 1 & 2 Letter")).

58. Guidant stated that there was no way of predicting whether "any particular device will fail." (*Id.* at 3). According to the June 17 Contak Renewal 1 & 2 Letter, fifteen reports of the malfunction had been confirmed, at least, one of which was fatal, and approximately 16,000 of the devices had been implanted worldwide. (*See id.* at 1).

59. Since the June 17 Contak Renewal 1 & 2 Letter, more reports of the malfunction have been confirmed by Guidant and at least three more deaths have been associated with the Contak Renewal 1 & 2 defect.

60. Guidant further advised physicians to consider performing a commanded shock of the ICD to confirm the integrity of the high-voltage delivery system, and warned physicians that Devices that had failed should be explanted and replaced with new Devices.

61. Guidant also stated that, in regard to the H135 Device, it had "implemented design and manufacturing corrective actions to address internal shorting within the device header. No devices manufactured after August 26, 2004 have exhibited this failure." (*Id.* at 3).

62. Once again, despite the fact that Guidant made manufacturing changes on or around August 26, 2004, which it represented had corrected the defect in the H135 device, Guidant failed to inform physicians, patients, and the public until the June 17 Contak Renewal 1 & 2 Letter.

63. In June 2005, Guidant recommended that physicians assess whether to replace the H135 device. In September 2005, Guidant recommended that physicians reassess device replacement "as a result of the increased projected rate of occurrence." (Guidant Corp., Advisory Update: Contak Renewal and Contak Renewal 2, Models H135 and H155 (Sept. 12, 2005)).

64. Guidant has stated that its estimation of the level of device malfunction in the H135 Device is likely to be understated because the actual number of clinical failures may be greater than the number reported and its predictive modeling is inherently uncertain.

65. The FDA has classified the action taken by Guidant with regard to the H135 Device as a Class I recall. The recall requires Guidant to disclose the device malfunction to individuals and doctors while providing additional instructions for safe use of the devices.

66. Meanwhile, Guidant had concluded that the polyimide insulation tubing used in the H135 device was susceptible to cracking that could result in short circuiting of the device.

67. In December 2005, the FDA reported that there had been at least five deaths associated with the defect in the H135 device and that additional clinical occurrences are likely.

68. At all times relevant to this action, Guidant knew, and had reason to know, that the H135 Device was not safe for the individuals for whom they were prescribed and implanted, because the device malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in certain individuals, catastrophic injuries and deaths.

69. Guidant has continued to issue advisories regarding the H135 Device. Guidant's latest advisory, on March 11, 2006, stated that H135 device may exhibit a decline in battery voltage related to an unexpected sustained, low level current. (*See* Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Guidant Renewal 3 RF & Renewal 4 RF (CRT-Ds) at 1 (Mar. 11, 2006)). Although Guidant claims that the defect can only occur during storage/shipment mode prior to implant, Guidant also states that it has confirmed that the internal low level current may occur "transiently" in normal use post implant.

70. Guidant has advised that the FDA may classify this communication regarding the H135 device as a recall.

VI. GUIDANT'S PAST AND PRESENT ILLEGAL AND REPREHENSIBLE CONDUCT

A. Guidant's Failure To Meet Basic Manufacturing & Regulatory Standards

71. The FDA conducted an inspection of Guidant's facilities during the time period of August 22, 2005 to September 1, 2005. At the conclusion of the inspection, the FDA issued a 483 Inspection Report ("FDA 483"), in which it detailed violations of federal regulations by Guidant. (*See* FDA 483 Inspection Report (Sept. 1, 2005) ("Sept. 1 FDA 483")).

72. The stated purpose of the FDA 483 is "to assist the firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration." (FDA 483 Inspection Report at 2 (Feb. 8, 2006) ("Feb. 8 FDA 483")).

73. Included in the Sept. 1 FDA 483 for Guidant were the following fifteen observations of violations noted by FDA:

(a) procedures for conducting quality audits were incomplete;

(b) "[n]ot all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified;"

(c) procedures were not completed and implemented for monitoring and controlling of process parameters for validated processes;

(d) "[a] process whose results cannot be fully verified by subsequent inspection and test has not been validated and approved according to established procedures;"

(e) "[p]rocedures to ensure that equipment is routinely maintained were not established;"

(f) "[d]uring production, component and device characteristics are not fully monitored and controlled;"

(g) "[p]rocedures for changes to methods were not complete;"

(h) management with executive responsibility has not ensured that an adequate and effective quality system has been implemented and maintained at all levels of the organization;

(i) "[s]oftware used as part of production and the quality system has not been fully validated for its intended use according to an established protocol," and electronic records which are used do not have requirements to ensure that they are trustworthy, reliable, and generally equivalent to paper records;

(j) "appropriate sources of quality data are not adequately analyzed to identify existing and potential causes of nonconforming product and other quality problems;"

(k) processes have not been approved and electronic records do not meet employee accountability/responsibility policy and signature manifestation requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records;

(l) "[t]he document control procedures do not designate an individual to review documents for adequacy and approve them prior to issuance;"

(m) "[r]ework and reevaluation activities have not been documented in the device history records;"

(n) "[d]ocument control procedures are not complete;" and

(o) the device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record. Feb. 8 FDA 483 at 1-6.

74. The findings of the FDA inspection of August and September 2005 confirm that Guidant was violating federal and state law in manufacturing the Device.

75. From December 2005 to February 2006, the FDA again inspected Guidant's manufacturing facilities and found further egregious violations of basic manufacturing standards fundamental to federal and state law. (*See* Feb. 8 FDA 483). Specifically, the FDA found that Guidant had failed to disclose the AVT device defects that it had known about since May 2002 and had attempted to correct through revised software implemented by May 2004. (*See id.*).

76. The FDA's inspections led to recalls of the H135 Device and specifically criticized Guidant's manufacturing and disclosure processes, stating that Guidant had failed to establish adequate procedures in violation of federal regulations.

77. Moreover, with respect to the H135 Device, Defendants failed to comply with FDA regulations and the Conditions of Approval relating to relevant PMA and PMA Supplements.

78. The claims alleged herein set forth sufficient facts to establish manufacturing defects with respect to the H135 Device.

79. No claims alleged herein are preempted under any provisions of the Medical Device Act or FDA regulations.

80. Guidant's failure to meet federal regulations applicable to medical devices and Guidant's other acts and omissions as described herein directly and proximately caused the Devices to be in violation of federal and state law, and proximately caused harm and injury to Plaintiffs.

B. Guidant's Concealment of the Device Defects

81. Guidant's failure to disclose accurately and adequately the known defects in the H135 Device and concealment of known defects from the FDA, the medical community, and from Plaintiffs constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

82. No Plaintiff could have discovered the existence of the short-circuit defect in the H135 Device until at least May 2005, when the first press reports regarding the defects were published.

83. It was not until June 17, 2005, that the public was officially notified by the FDA that the agency was recalling H135 Device. At no point prior to June 17, 2005, did Guidant notify any Plaintiff, the medical community, or the public that the H135 Device was defective.

84. Meanwhile, although Guidant regularly issued Product Performance Reports purporting to disclose information regarding the Device, it was not until late 2005 that such Product Performance Reports included any information from which a reader could discern that Guidant was aware of potentially life-threatening malfunctions that could occur in the Device.

85. Guidant's failure to properly disclose the known defects in the H135 Device and Guidant's active concealment of the known defects from the FDA, the medical community, and Plaintiffs constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

86. Guidant is estopped from relying on the statute of limitations defense because it actively concealed the ICD defects by suppressing reports, failing to follow through on FDA notification regulations, and failing to disclose known defects to the medical community, the public, or the Plaintiffs.

87. Instead of revealing the defects, Guidant continued to represent the H135 Device as safe for its intended use.

88. Guidant's conduct, as described in the preceding paragraphs, amounts to conduct that Guidant must have realized was dangerous, heedless and reckless, without regard to the consequences or to the rights and safety of Plaintiffs.

89. At all times relevant to this action, Guidant knew, and had reason to know, that the H135 Device was not safe for the individuals for whom it was prescribed and implanted, because

the Device short circuited and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in some individuals, catastrophic injuries and deaths.

90. As a result of defects in both the design and the manufacture of the H135 Device (defects which Guidant concealed), Guidant knew and had reason to know that the Device would fail to function properly, and have a significantly decreased life expectancy.

91. Further, Guidant knew and had reason to know that the life expectancy of the Device was significantly shorter than that which Guidant represented to the FDA, the medical community, and those in whom the Device was implanted. Guidant affirmatively concealed and suppressed the true information about the life expectancy and reliability of the Device.

92. At all times relevant to this action, Guidant knew, and had reason to know, that the H135 device was not safe and effective for the individuals for whom it was prescribed and implanted, because after short circuiting the Device could fail to function and the internal memory within the Device would be erased, thereby concealing both evidence of the short circuit and any medical memory of the patient's arrhythmias in the period preceding the short-circuiting episode. This malfunction prevents the doctor from properly reviewing the patient's heart rhythm history, and from providing related medical services, such as possibly adjusting necessary medication. Further, while Guidant has recommended that doctors consider inducing shocks to their patients to determine if the devices are already malfunctioning, it is otherwise impossible for doctors to test these devices to determine whether they will short circuit and fail to perform as intended.

93. Nonetheless, in its June 24, 2005 letter to patients, Guidant continued to falsely reassure the public that "[t]he safety and well being of patients is foremost in our minds" and that Guidant maintains a "steadfast dedication to patients." (Letter from Allan Gorsett, Vice President, Reliability and Quality Assurance, Guidant Corp., to Patients with Contak Renewal 1 & 2 Devices at 1 (June 24, 2005)).

94. The Independent Panel, however, found that Guidant's quality control processes— particularly with respect to post-market evaluation of the Device— were not consistent with appropriate concern for patients and quality. For example, the Independent Panel concluded that no

medical professionals are involved in Guidant's post-market surveillance, that positions critical to the assessment of Device defects were consistently understaffed by Guidant, and that the few individuals who were assigned to the important task of assessing Device defects generally lacked sufficient appropriate training and expertise.

VII. THE LIFE AND DEATH OF RAYMOND SAAD

95. Mr. Saad had a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. On or about October 7, 2004, Mr. Saad was implanted with a Guidant Contak Renewal cardiac resynchronization therapy defibrillator, also known as the H135 Device.

96. After October 7, 2004, Mr. Saad first learned that the Guidant Contak Renewal defibrillator implanted in his body had an irregularity that could result in its failure to function. Mr. Saad suffered extreme emotional distress as a result of the knowledge of the defective nature of his implanted H135 Device, and knowledge that he might have, at any time, been fatally injured because of its malfunction. In addition, he was very concerned that he might get a life-threatening infection of the heart (endocarditis) as a result of the replacement surgery.

97. On or about October 30, 2005, Mr. Saad died as a result of heart failure, attributable directly to the defects in the H135 Device implanted in him.

VIII. THE ACTS AND OMISSIONS AT THE MORTUARY

98. At the direction of Mr. Saad's widow, Seta Saad, Mr. Saad's body was transported to a mortuary in San Francisco. That mortuary was owned and operated by Ashley & McMullen and Ashley & McMullen-Wing Sun Mortuary. Within a day following transport, Ms. Saad spoke with a representative of Guidant on the phone. She expressed concerns regarding possible defects in the device. The Guidant representative requested if Guidant could perform a non-invasive test or reading of the device, which was still implanted in Mr. Saad's body. She said this would be permissible *as long as she could be present.*

99. Following the phone conversation between Ms. Saad and Guidant, Guidant employee Craig Lawrence contacted the mortuary and informed persons there that Guidant had authority from Ms. Saad to perform a test or reading of the HR 135 device. Without confirming with Ms. Saad

beforehand, the Mortuary agreed to allow Guidant to perform the test. The test was performed soon thereafter by Guidant employee David McCallum. No one informed Ms. Saad that the test would be taking place, and she was not present while the test was performed.

100. The day following the test or reading of the device, Guidant sent another agent to remove the device from Mr. Saad's body. The Guidant agent who performed the removal was a person named Joseph Lopez. The extracted device was taken from the Mortuary by Guidant's agent and returned by him to Guidant. Guidant maintains custody of the device to this day.

101. Neither Ms. Saad nor Christian Saad granted any authority to anyone to extract the device.

CLAIMS FOR RELIEF

COUNT I

STRICT LIABILITY

DESIGN AND/OR MANUFACTURING DEFECT

(By All Plaintiffs Against Guidant Defendants)

102. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

103. The H135 Device is defectively designed and/or manufactured because the foreseeable risks of mechanical malfunction and failure outweigh the benefits associated with the Device.

104. The Device was designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 *et seq.* (hereinafter "FDCA"). The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the Devices were not in conformity with applicable FDCA regulations. The FDA has also concluded that the facilities or controls used by Defendants did not meet the FDCA regulations.

105. The Device was expected to and did reach the Plaintiffs without substantial change or adjustment to its mechanical function before implantation.

106. Defendants knew or should have known of the design and/or manufacturing defect and the risk of serious bodily injury that exceeded the benefits associated with the design of the Devices.

107. Furthermore, the Device and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

108. The Device was defective due to inadequate warnings or instruction because Defendants knew or should have known that the Device created a high risk of bodily injury and serious harm. Defendants failed to adequately and timely warn consumers of this risk.

109. The Device was inherently dangerous for its intended use due to design and/or manufacturing defect and improper functioning. Defendants are therefore strictly liable.

110. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses, and other damages for which they are entitled to compensatory, equitable, and declaratory relief in an amount to be proven at trial.

111. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT II

STRICT LIABILITY – FAILURE–TO–WARN

(By All Plaintiffs Against Guidant Defendants)

112. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

113. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Devices, including the H135 Device. Defendants designed, manufactured, assembled and sold these Devices to medical professionals and their patients, knowing that they would then be implanted in patients with heart disease and disorders.

114. Defendants distributed and sold the Devices in the condition in which they left their place of manufacture, in their original form of manufacture, which included the defects described herein. The Devices were expected to and did reach Plaintiffs without substantial change in their

condition as manufactured and sold by Defendants. At no time did Plaintiffs have reason to believe that the Devices were in a condition not suitable for their proper and intended use among the patients in whom they were to be implanted.

115. The H135 Device that was designed, developed, tested, manufactured, marketed, and sold or otherwise placed into the stream of commerce by Defendants was in a dangerous and defective condition and posed a threat to any user or consumer of the Device. Plaintiffs were and are in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of the Device.

116. The H135 Device was implanted and used in the manner for which it was intended, that is, for the detection, correction, and prevention of serious and/or life-threatening harm through surgical implantation. This use has resulted in injury to Plaintiffs.

117. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of the Device. Further, in no way could Plaintiffs have known that Defendants had designed, developed, and manufactured the Device in such a way as to increase the risk of harm, injury or death to the recipients of the Device.

118. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

119. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT III

NEGLIGENCE

(By All Plaintiffs Against Guidant Defendants)

120. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

121. At all relevant times, Defendants owed a duty of ordinary care to Plaintiffs. This duty is embodied in *California Civil Code* § 1714, and in the common law of this State.

122. Defendants breached their duty of reasonable care to Plaintiffs by incorporating a defect into the design of the Devices, thereby causing Plaintiffs' injuries.

123. Defendants breached their duty of reasonable care to Plaintiffs by manufacturing and assembling the Devices in such a manner that they could short circuit and/or otherwise fail to operate and malfunction and expose Plaintiff Raymond Saad to life-threatening physical trauma.

124. Defendants breached their duty of reasonable care to Plaintiffs by failing to notify and warn the FDA, Plaintiff Raymond Saad and his treating physicians at the earliest possible date of known design or manufacturing defects in the H135 Device.

125. Defendants breached their duty of reasonable care to Plaintiffs by failing to obtain authorization from Mrs. Saad or Christian Saad to inspect the body of Raymond Saad and perform tests without her being present. They breached their duty, also, by extracting the defective device from Mr. Saad's body without obtaining permission from Ms. Saad or Christian Saad.

126. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances.

127. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe emotional distress, economic losses and other damages for which they are entitled to compensatory, equitable and declaratory relief in an amount and to an extent to be proven at trial.

128. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT IV

NEGLIGENCE PER SE

(By All Plaintiffs Against Guidant Defendants)

129. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

130. Defendants have an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising,

preparing for use, warning of the risks and dangers of the Devices, and otherwise distributing the Devices.

131. Defendants' acts constitute an adulteration, misbranding, or both, as defined by the Federal FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom and from parallel state law requirements, under theories of negligence per se.

132. Plaintiffs, as purchasers of the Defendants' Devices, are within the class of persons the statutes and regulations described in the previous paragraph are designed to protect and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

133. Furthermore, by gaining access to the body of Raymond Saad and extracting the defective device from that body without obtaining the consent of Mr. Saad's successors-in-interest, Defendants violated *Penal Code* §§ 487 and 642, and *Health and Safety Code* § 7114, thereby subjecting themselves to civil liability for all damages arising therefrom.

134. Plaintiffs, as successors-in-interest and next-of-kin of Raymond Saad, are within the class of persons the statutes identified in the previous paragraph are designed to protect and Plaintiffs' injuries are the type of harm these statutes are designed to prevent.

135. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory, equitable, and declaratory relief in an amount to be proven at trial.

136. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT V

NEGLIGENCE

(By Plaintiffs Seta Saad and Christian Saad Against Ashley & McMullan and Ashley & McMullan-Wing Sun)

137. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

138. At all relevant times, Defendants owed a duty of ordinary or reasonable care to Plaintiffs to avoid causing them injury. This duty is embodied in *California Civil Code* § 1714, and in the common law of this State.

139. Defendants breached their duty of ordinary or reasonable care to Plaintiffs by permitting Guidant agents and employees access to Mr. Saad's body for the purpose of performing tests or readings on the implanted H135 Device without obtaining the Plaintiffs' approval beforehand.

140. Defendants breached their duty of ordinary or reasonable care to Plaintiffs by permitting Guidant agents and employees access to Mr. Saad's body for the purpose of extracting the implanted H135 Device from that body without obtaining the Plaintiffs' approval beforehand.

141. Defendants breached their duty of ordinary or reasonable care to Plaintiffs by permitting Guidant agents and employees to take the extracted H135 Device from the mortuary.

142. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances.

143. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained damage, including severe emotional distress and monetary loss, for which they are entitled to compensatory, equitable, and declaratory relief in an amount to be proven at trial.

144. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT VI

BREACH OF IMPLIED WARRANTY

(By All Plaintiffs Against Guidant Defendants)

145. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

146. Defendants impliedly warranted that the H135 Device, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were merchantable and fit and safe for ordinary use. Defendants further impliedly warranted that their Device, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were fit for their particular purposes.

147. Defendants' Device was defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiffs to severe and permanent injuries and death. Therefore, Defendants breached the implied warranties of merchantability and fitness for a particular purpose when their Device was sold to Plaintiffs, in that the Device was defective and had short circuited or otherwise failed to function, or was subject to an enhanced risk that it would not function, as represented and intended.

148. Any disclaimers of implied warranties are ineffectual as they were not provided to Plaintiffs or otherwise made known to Plaintiffs. In addition, any such disclaimers are unconscionable.

149. Any purported written warranty fails of its essential purpose.

150. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiffs have sustained economic losses and other damages for which they are entitled to compensatory and equitable relief in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and damages to Plaintiffs in that it, in effect, provides no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential damages is unconscionable.

151. Defendants are liable to Plaintiffs jointly and/or severally for all damages to which Plaintiffs are entitled by law.

COUNT VII

BREACH OF ASSUMED CONTRACTUAL WARRANTY OBLIGATIONS

(By All Plaintiffs Against Guidant Defendants)

152. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

153. Defendants have acknowledged their obligations as first-party insurer by providing express and/or implied warranties directly to consumers of their products, and specifically the Devices.

154. Defendants have an obligation to repay Plaintiffs for all costs incurred with the H135 Device because they have acknowledged a responsibility under their warranties to make payment with regard to the Device.

155. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have suffered damages including health care costs that have been paid by them in an amount to be proven at trial.

156. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT VIII

FRAUD

(By All Plaintiffs Against Guidant Defendants)

157. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

158. Contrary to Defendants' representations to Plaintiffs, Defendants' H135 Device could cause severe injury or death. In fact, short circuits of the Device were known to Defendants to have occurred for years. At all times during the course of dealing between Defendants and Plaintiffs, directly or through their physicians or other agents, Defendants misrepresented that the Device was safe and effective for its intended use by affirmative misrepresentation; actively concealed and knowingly or recklessly omitted material facts regarding the safety and effectiveness of the Device; and/or by their course of conscious or intentional conduct succeeded in selling and marketing dangerous, defective and ineffective medical devices to be implanted in the human body.

159. Defendants, by concealment or other action, intentionally prevented Plaintiffs, Plaintiffs' physicians, and Plaintiffs' other agents from acquiring material information regarding the lack of safety and effectiveness of the Device, and are subject to the same liability to Plaintiffs for Plaintiffs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Device's lack of safety and effectiveness, and dangers and defects, as though Defendants had affirmatively stated the non-existence of such matters that Plaintiffs were

thus prevented from discovering, and therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, *Restatement (Second) of Torts* § 550 (1977).

160. Defendants were under a duty and failed to discharge their duty to exercise reasonable care to disclose to all Plaintiffs the defective nature of the Device, of which they had special knowledge not available to Plaintiffs, and as to which they made affirmative representations in violation of all applicable laws, including, *inter alia*, *Restatement (Second) of Torts* § 551 (1977).

161. Defendants' misrepresentations, concealment, suppression and omissions were made willfully, wantonly, uniformly, deliberately or recklessly, in order to induce Plaintiffs to purchase Defendants' Device and/or agree to have the Device implanted into Plaintiff Raymond Saad's body, and Plaintiffs did reasonably and justifiably rely upon the material misrepresentations and omissions made by the Defendants about the Device when agreeing to purchase and/or have the Devices implanted.

162. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiffs have suffered personal injuries and/or pecuniary losses and economic damages, including health care costs that have been paid by them, or on their behalf, in an amount to be proven at trial.

163. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT IX

CONSTRUCTIVE FRAUD

(By All Plaintiffs Against Guidant Defendants)

164. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

165. At the time of selling the Device to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the H135 Device, which knowledge was not possessed by Plaintiffs, and Defendants thereby held a position of superiority over Plaintiffs.

166. Through their unique knowledge and expertise regarding the defective nature of the H135 Device, and through their marketing of this device to be implanted in the human body and statements to physicians and their patients in advertisements, promotional materials, and other

communications, Defendants professed to Plaintiffs that they were in possession of facts demonstrating that the Device was safe and effective for its intended use and was not defective.

167. Defendants' representations to Plaintiffs were unqualified statements made to induce Plaintiffs to purchase the Device, and Plaintiffs relied upon the statements when purchasing the device and having it implanted.

168. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and engaged in constructive fraud in their relationship with Plaintiffs. Plaintiffs reasonably relied on Defendants' representations.

169. As a direct and proximate result of Defendants' constructive fraud, Plaintiffs have suffered personal injuries, pecuniary losses, and/or economic damages, including health care costs that have been paid by them, and on their behalf, in an amount to be proven at trial.

170. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT X

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

(By All Plaintiffs Against Guidant Defendants)

171. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections; and the Negligence Count of Plaintiffs' Complaint as if fully set forth herein.

172. Defendants carelessly and negligently manufactured, marketed, and sold the H135 Device to Plaintiffs, carelessly and negligently concealed its defects from Plaintiffs, and carelessly and negligently misrepresented the quality, safety, and usefulness of the Device. Defendants should have realized that such conduct involved an unreasonable risk of causing emotional distress to reasonable persons, that might, in turn, result in illness or bodily harm.

173. Defendants owed a duty to treating physicians and ultimate End Users of the Device, including Plaintiffs, to accurately and truthfully represent the risks of the Device.

174. Defendants breached that duty by misrepresenting and/or failing to issue adequate warnings of the risks of the Device to the Raymond Saad's treating physicians and to the Plaintiffs.

175. As a direct and proximate result of Defendants' wrongful conduct and breach of duty, Plaintiffs have sustained and will continue to sustain severe emotional distress either due to physical injury or a rational fear of physical injury or death or to the actual death of Raymond Saad, and are entitled to recovery of damages in an amount to be proven at trial.

176. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT XI

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

(By Seta Saad and Christian Saad Against Ashley & McMullan and Ashley & McMullan-Wing Sun Mortuary)

177. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections; and the Negligence Count of Plaintiffs' Complaint as if fully set forth herein.

178. Defendants owed a duty of ordinary or reasonable care to Plaintiffs to avoid causing them, via their actions or omissions, emotional distress.

179. Defendants carelessly and negligently allowed Guidant's agents and employees access to the body of Raymond Saad for the purpose of conducting tests or readings and extracting the defective H135 Device.

180. The carving into the body of Raymond Saad amounted to the desecration of a corpse, which all cultures, in all times, have held to be an extreme taboo. The desecration of a corpse is a vile act. The act is one that gives rise to extreme revulsion. That revulsion is significantly greater when felt by one whose loved one's body has been desecrated. With such revulsion is added extreme heart-ache, anxiety, anger, dismay and a host of other emotions.

181. As a direct and proximate result of Defendants' wrongful conduct and breach of duty, Plaintiffs have sustained and will continue to sustain severe emotional distress due to the continuing sense of revulsion and anxiety and are thus entitled to damages in an amount to be proven at trial.

182. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT XII

INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

(By All Plaintiffs Against Guidant Defendants)

183. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections; and the intentional wrongdoing allegations of Plaintiffs' Complaint as if fully set forth herein.

184. Defendants' conduct directed toward Plaintiffs, was, by act and omission, intentional, knowing, and/or reckless, and evidenced a willful intention to inflict injury upon Plaintiffs, or a reckless disregard for the rights and interests of Plaintiffs equivalent to an intentional violation of them. This conduct exceeded all bounds usually tolerated by decent and civilized society and was directed toward an inherently vulnerable cardiac patient and his family.

185. As a direct, proximate, intended, known, natural, and foreseeable result of Defendants' conduct, Plaintiffs were and are suffering injury in the form of serious, severe, extreme emotional distress that no reasonable person could or should be expected to endure.

186. Defendants are liable and accountable at law to compensate Plaintiffs for such emotional distress, and for all such damages and injuries resulting therefrom and related thereto.

187. Defendants' conduct was intentional, knowing, oppressive, fraudulent, malicious, extreme and outrageous, and done in conscious and reckless disregard of Plaintiffs' rights, thereby entitling Plaintiffs to seek to assert claims for exemplary and punitive damages, at the appropriate time under governing law, in an amount sufficient, necessary and appropriate to punish Defendants for their reprehensible conduct and to deter them and others from such conduct in the future.

188. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT XIII

GROSS NEGLIGENCE/MALICE

(By All Plaintiffs Against Guidant Defendants)

189. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

190. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and reckless disregard for the rights of others, the public, and Plaintiffs for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct: was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

191. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will, as noted, seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT XIV

UNFAIR COMPETITION AND UNFAIR BUSINESS PRACTICES

(*California Business and Professions Code* Sections 17000 et seq. and 17200 et seq.)

(By all Plaintiffs Against Guidant Defendants)

192. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

193. Defendants are "persons" as defined under *California Business and Professions Code* § 17021.54. Each of the directors, officers and/or agents of Defendants are equally responsible for the acts of the others as set forth in *California Business and Professions Code* § 17095.55.

194. Defendants manufactured and sold various heart regulating and heart monitoring devices, including the H135 Device, to the "public" as defined in *Business and Professions Code* §§ 17022 and 17024.

195. Plaintiffs are informed and believe that for the last four years, Defendants have unfairly and unlawfully designed, manufactured, marketed, distributed and sold the H135 Device to the public. Plaintiffs are informed and believe, that Defendants' conduct occurred in violation of Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 *et seq.* and other portion of the federal regulatory scheme described in Sections IV and VI of this Complaint.

196. Defendants' failure to abide by the aforementioned federal regulatory scheme is either unfair and/or an offense punishable by statutory fine and/or imprisonment for each violation. Defendants' acts constitute a continuing and ongoing unfair and unlawful activity prohibited by *California Business and Professions Code* sections 17200 et seq., and justify the issuance of an injunction, the making of restitution and the imposition of other equitable relief pursuant to *Business and Professions Code* § 17203, as to Guidant Corporation, Guidant Sales Corporation, and Boston Scientific Corporation, and each of these Defendants' managing agents and officers.

197. As set forth below, Plaintiffs are informed and believe that by failing to abide by the aforementioned federal regulatory scheme, Defendants have engaged in business within the State of California selling products to the public, as defined in *Business and Professions Code* §§§ 17026, 17029, and 17073, for the purpose of injuring competitors and/or destroying competition in violation of *Business and Professions Code* § 17043.

198. Plaintiffs are informed and believe that Defendants have instructed and directed its directors, officers, employees, and/or agents to intentionally and unlawfully violate the aforementioned federal regulatory scheme as a means of gaining an unfair advantage over their competitors in violation of *Business and Professions Code* § 17047. The advantage gained from violation of the Unfair Business Practices Act accrues, among other ways, in the form of a lower cost of doing business and an increased margin of profit.

199. Plaintiffs are informed and believe that Defendants committed further violations of the law in an effort to keep hidden from Plaintiffs and the general public the defective nature of the

H135 Device. Defendants did this by falsely claiming authority to conduct an autopsy on the body of Raymond Saad, and then wilfully and maliciously taking the defective H135 Device from his body. This conduct amounted to grand larceny, theft from a corpse, and unlawful conduct of an autopsy, as defined, respectively, in *California Penal Code* § 487, *California Penal Code* § 642 and *California Health and Safety Code* § 7114, and the relevant case law of this State.

200. As a result of these acts and omissions by Defendants, the Plaintiffs, on information and belief, allege that Defendant was able to unfairly compete with other entities engaged in the business of selling heart regulating and heart monitoring devices in the State of California in violation of *Business and Professions Code*, §§ 17000 et seq. and §§17200 et seq. Due to these unfair, fraudulent and/or unlawful business practices, Defendants have gained a competitive advantage over other comparable business entities doing business in the State of California who adhere to the aforementioned federal regulatory scheme.

201. The victims of these unfair and/or unlawful business practices include the Plaintiffs, Defendants' competitors, and the consuming public. Plaintiffs are informed, believe and allege that Defendant performed the above-mentioned acts with the intent of gaining an unfair competitive advantage and thereby injuring Plaintiffs, other competitors, and the consuming public.

202. Each breach of its duty under the aforementioned federal legal scheme in violation of *Business and Professions Code* § 17100 and other statutes is a crime punishable by both a statutory fine and imprisonment. These failures constitute continuing and ongoing unlawful activities prohibited by *Business and Professions Code* sections 17000 et seq. and 17200 et seq. and justify the issuance of an injunction. All such remedies are cumulative pursuant to *Business and Professions Code* § 17205.

203. Pursuant to *Business and Professions Code* § 17203, Plaintiffs, in their individual and representative capacities, request restitution and/or disgorgement of all money wrongfully obtained by Defendants which had been paid to them by any of the Plaintiffs, in violation of *Business and Professions Code* sections 17000 et seq. and sections 17200 et seq. Furthermore, Plaintiffs request attorneys' fees and costs pursuant to *California Code of Civil Procedure* § 1021.5, and from the common law doctrine from which that statute was derived, upon a showing of proof, among other

things, that they have acted in the public interest and that a significant benefit has been conferred on the general public and/or a large class of persons, as set forth in the *Private Attorney General Act* and the common law of this State.

204. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT XV

CONVERSION

(By Plaintiffs Against Guidant Defendants)

205. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

206. The H135 Device was purchased by Raymond Saad and Seta Saad from the Defendants. At the time of his death, Mr. Saad had lawful title to and possession of the H135 Device. Upon his death, title remained with his estate. The device, however, remained in Mr. Saad's body.

207. Following Mr. Saad's death, his body was entrusted to the mortuary owned and operated by Defendants Ashley & McMullen and Ashley & McMullen-Wing Sun. While the body reposed at the mortuary, the Guidant Defendants contacted the mortuary and falsely claimed to have obtained Seta Saad's permission to observe the body and take readings from the H135 Device. This, the Mortuary allowed.

208. In addition to taking readings from the H135 Device, the Guidant Defendants wilfully and maliciously extracted the device from Mr. Saad's body and took it away from the Mortuary. The Defendants retain possession of the device to this day.

209. The taking of the H135 Device from Mr. Saad's body was not authorized or approved, either verbally or in writing, by Plaintiffs Seta Saad and Christian Saad. The device belonged to these two Plaintiffs, individually and as the Representatives and Successors-in-Interest of Mr. Saad. As a result, the Defendants' taking and retention of the H135 Device constitutes Conversion.

210. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs, in their individual and representative capacities, have suffered damages for which they are entitled to compensatory, equitable and declaratory relief in an amount to be proven at trial.

211. Defendants are liable to the Plaintiffs jointly and/or severally for all relief to which the Plaintiffs are entitled by law.

COUNT XVI

LOSS OF CONSORTIUM

(By Seta Saad and Christian Saad Against Guidant Defendants)

212. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

213. For the reasons set forth herein, the surviving Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

214. For the reasons set forth herein, the surviving Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love, and affection.

215. For Seta Saad, Plaintiffs allege her marital relationship with Raymond Saad has not merely been impaired and depreciated, but destroyed.

216. The surviving Plaintiffs have suffered great emotional pain and mental anguish.

217. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe emotional distress, economic losses, and other damages for which they are entitled to compensatory, equitable, and declaratory relief in an amount to be proven at trial.

218. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

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COUNT XVII

WRONGFUL DEATH

(Cal. Code of Civ. Proc., Pt. 2, Tit. 3, Chap. 4)

(By Seta Saad and Christian Saad Against Guidant Defendants)

219. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

220. Raymond Saad died as a result of defects in Defendants' H135 Device and is survived by his widow Seta Saad and son Christian Saad.

221. The representatives/administrators of Raymond Saad's estate bring this claim on behalf of the Raymond Saad's lawful heirs.

222. Defendants' wrongful conduct has proximately caused Raymond Saad's heirs to suffer the loss of Mr. Saad's companionship, services, society, marital association, love and consortium.

223. Raymond Saad's estate's representatives brings this claim on behalf of Mr. Saad's lawful heirs for these damages and for all pecuniary losses sustained by the heirs.

224. Raymond Saad's estate's representatives further plead all wrongful death damages allowed by statute in the state or states in which the causes of action accrued.

COUNT XVIII

SURVIVAL ACTION

(Cal. Code of Civ. Proc., Pt. 2, Tit. 3, Chap. 4)

(By All Plaintiffs Against Guidant Defendants)

225. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

226. As a direct and proximate result of the conduct of Defendants outlined above, Raymond Saad, prior to his death, suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well as loss of ability to earn money.

227. The representatives/administrators of Raymond Saad's estate bring this claim for damages on behalf of Mr. Saad's estate and Mr. Saad's beneficiaries.

228. The representatives/administrators of Raymond Saad's estate further plead all survival damages allowed by statute in the state or states in which the causes of action accrued.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and in their representative capacities, pray for judgment against Defendants as follows:

1. For compensatory damages according to proof;
2. For restitution as requested pursuant to *Business & Professions Code* § 17200 et seq;
3. For leave to seek punitive or exemplary damages against Defendants, at the appropriate time under governing law as determined by the Court, consistent with the degree of Defendants' reprehensibility and the resulting harm or potential harm to Plaintiffs, and in an amount sufficient to punish Defendants and deter others from similar wrongdoing;
4. For a disgorgement of profits and restitution of all costs related to the defective Device;
5. For injunctive relief;
6. For an award of attorneys' fees and costs;
7. For prejudgment interest and the costs of suit;
8. For such other and further relief as this Court may deem just and proper; and
9. For preference in setting the matter for trial pursuant to *Cal. Civ. Proc. Code* § 36.

DATED: 29 October 2007

THE EDGAR LAW FIRM

Donald S. Edgar, Esq.
Jeremy R. Fietz, Esq.
Rex Grady, Esq.